

CRITERIA FOR PRIOR AUTHORIZATION

CFTR (cystic fibrosis transmembrane conductance regulator) Modulator

PROVIDER GROUP	Pharmacy
MANUAL GUIDELINES	The following drugs require prior authorization: Kalydeco (ivacaftor) Orkambi (lumacaftor/ivacaftor)

CRITERIA FOR KALYDECO: (must meet all of the following)

- Patient must be at least 2 years old.
- Patient must have a diagnosis of cystic fibrosis.
- Patient must have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H
- Patient must not be homozygous for the *F508del* mutation in the CFTR gene.

LENGTH OF APPROVAL: 12 months

CRITERIA FOR ORKAMBI: (must meet all of the following)

- Patient must have a diagnosis of Cystic Fibrosis.
- Patient must be homozygous for *F508del* mutation in the CFTR gene.
- Patient must 12 years of age or older.

LENGTH OF APPROVAL: 12 months

***Note:** Providers may be referred to the Cystic Fibrosis Foundation website for information regarding genetic testing to patients with a confirmed diagnosis of cystic fibrosis:

http://www.cff.org/treatments/Therapies/Kalydeco/#Is_Kalydeco_only_for_G551D.